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March 2, 2023

The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106-1797

VIA ELECTRONIC FILING and FEDERAL EXPRESS

Re: *Arbutus Biopharma Corp., et al. v. Moderna, Inc., et al.*
C.A. No. 22-252 (MSG) (D. Del.)

Dear Judge Goldberg:

Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") respectfully submit this letter to address the impact of the Government's Statement of Interest (D.I. 49, "SOI") on Moderna's Partial Motion to Dismiss (D.I. 16) and on the scheduling of this matter.

Long before filing this suit, Plaintiffs knew Moderna's sales to the U.S. Government under the August 11, 2020 Supply Contract were subject to Section 1498. That contract was publicly available. And Moderna specifically told Plaintiffs a year earlier that those sales to the U.S. Government were "subject to 28 U.S.C. § 1498." D.I. 17, Ex. B (Ryan Decl.) ¶ 8; *see also* Compl. ¶ 50 n.16 (citing to Ryan Decl.). Knowledge of the Government's acceptance of liability notwithstanding, Plaintiffs chose to sue the wrong party in the wrong court for sales under that contract. And now, in the face of the Government's Statement of Interest confirming the "Government's acceptance of liability," Plaintiffs persist in asking this Court to require the parties to proceed with fact and expert discovery on claims that belong in the Court of Federal Claims.

Based on the Government's unequivocal confirmation that it accepted any liability for vaccine procured under the '-0100 Contract, Moderna respectfully asks this Court to dismiss those claims. The parties should proceed through discovery in this action only on the remaining claims that belong in this Court.

I. PLAINTIFFS' CLAIMS UNDER THE '-0100 CONTRACT SHOULD BE DISMISSED

Plaintiffs' claims are based on Moderna's sales to the U.S. Government and later sales "to foreign governments or other foreign entities." Compl. ¶¶ 51, 53. Because Moderna "supplied

COVID-19 Vaccine to the U.S. Government pursuant to a contract" (W911QY-20-C-0100, the "'-0100 Contract"), for the Government and with the Government's express authorization and consent, Moderna moved to dismiss Plaintiffs' claims under § 1498(a) based on the provision of its COVID-19 Vaccine under that contract. D.I. 17 (Mot.) at 2; D.I. 23 (Reply Br.) at 9–10.

As the Government notes in its Statement of Interest (SOI at 4), Moderna and the U.S. Army later executed a second contract, W58P05-22-C-0017, on July 28, 2022—after briefing was complete on Moderna's Partial Motion to Dismiss. Moderna only moved to dismiss sales under the '-0100 Contract, because that is the only contract in which the Government provided its authorization and consent. If the Court grants Moderna's Partial Motion to Dismiss, all claims based on sales outside of the '-0100 Contract would remain in the litigation, including sales to the Government under the '-0017 Contract and sales to foreign governments.

Section 1498(a) has two requirements: the allegedly infringing use must be "for the Government" and with "the authorization or consent of the Government." *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007).[1] The Court denied Moderna's Partial Motion on November 2, 2022. D.I. 31. With respect to the first requirement, the Court found that "[a]bsent clear language, either in the Complaint or the Contract, establishing that the development of the vaccine was 'for the Government,' I find that this dispute is not appropriate for resolution in a Rule 12(b)(6) motion." *Id*. at 13. With respect to the second requirement, although the Court recognized that the '-0100 Contract incorporates "48 C.F.R. § 52.227-1(a) (2020)," it noted that "[t]he contract before me here is incomplete and heavily redacted" and "the Government has not filed any statement of interest indicating its express consent to the accused activities." *Id.* at 15. The Government's Statement of Interest has resolved both of these issues.

A. Moderna Supplied Doses to the U.S. Government "for the Government"

Moderna agrees with the Government that "where the Government elects to include a contract provision expressly providing its authorization and consent, as it has done here, that decision is appropriately viewed as reflecting the Government's determination that the contract is for the Government's benefit." SOI at 9.[2] Although this is clear on the face of the '-0100 Contract, the Government's Statement removes any doubt. The Government is in the best position to decide what is for its benefit, and the Government has made that determination by including the FAR clauses in the '-0100 Contract, and now through its Statement of Interest. Where the Government has stated its position that goods or services were provided "for the Government," courts have accepted that without the need for discovery. *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1376 (Fed. Cir. 2009) (finding that "representations to this Court that

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[1] Unless otherwise noted, internal quotation marks and citations are omitted from quotes.

[2] The Government's express authorization and consent distinguishes this case from *Larson* and *Advanced Software Design*, where the courts engaged in detailed analysis of the "for the government" requirement. In those cases, no supply contracts existed between the Government and the supplier. *Advanced Software Design*, 583 F.3d at 1376, 1378; *Larson v. United States*, 26 Cl. Ct. at 368. And in *Larson*, the Government expressly opposed the plaintiffs' argument that the reimbursement of medical splints was for its benefit. 26 Cl. Ct. at 369.

the accused activities are 'for the United States' and with its authorization and consent" reinforced applicability of 1498(a)); *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1363 (Fed. Cir. 2014) ("We also note that [USG] has unequivocally stated its position that suit under § 1498(a) is appropriate here. . . . (. . .'This is use "***for the Government.***" . . .'). Although the government's statement is not dispositive, it reinforces our conclusion that the United States has waived sovereign immunity in this case and, therefore, that IRIS's exclusive remedy is suit for recovery against the United States under § 1498(a).").

And even if the Court examines the "for the benefit" prong, the Government has now confirmed that it "received the benefit of its contract, namely, procuring the vaccine that it then offered for free public distribution in an effort to thwart the COVID-19 pandemic." SOI at 9–10. That benefit is clear based on the Complaint and the '-0100 Contract itself: "reduc[ing] SARS-CoV-2 transmission" and "mitigating the impact of COVID-19 on the nation and its people." D.I. 17, Ex. A at 19; Feb. 16, 2023 Hr'g Tr. at 9:13–16 (Plaintiffs' counsel stating, "The part of the Contract that Moderna and the Government don't want to talk about also ***says it's for the Government*** and for the U.S. population."); Compl. ¶ 1 ("The impact of the COVID-19 pandemic, one of the greatest public health challenges in modern history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's."). References in the Complaint to the benefit of individual patients change nothing, because, as this Court recognized, "[t]he Government's benefit need not be the 'primary purpose' of a government contract," and "[l]ikewise, the Government need not be the sole beneficiary." D.I. 31 at 8 (citing *IRIS Corp.*).

In *Sevenson*, the Federal Circuit explained that where, as here, "infringing activity has been performed by a government contractor pursuant to a government contract and for the benefit of the government, courts have all but bypassed a separate inquiry into whether infringing activity was performed 'for the Government'" and "the inquiry has [been] reduced to the 'very simple question' of whether the plaintiffs 'establish that the government authorized or consented to the . . . infringement . . . , if such infringement in fact occurred.'" 477 F.3d at 1366. There, the Federal Circuit considered "whether the infringing method was practiced 'for the Government,'" and found that the "question [was] answered in the affirmative by the observation that the government sought and received hazardous waste remediation services at the Colonie site." *Id*. In other words, the question is reduced to whether the Government received the goods or services that it contracted for and provided its authorization and consent. It is clear from the face of the Complaint and the '-0100 Contract that the Government provided its authorization and consent and did in fact receive the goods it contracted for, confirming that Moderna's provision of vaccine was "for the government." Compl. ¶ 51; D.I. 17, Ex. A at 46.

B. Moderna Had "the Authorization and Consent of the Government"

As this Court found, the '-0100 Contract expressly incorporated by reference FAR clauses 52.227-1, providing the Government's authorization and consent. D.I. 31 at 15; *see* FAR 27.201-1(b) ("The Government may expressly authorize and consent to a contractor's use or manufacture of inventions covered by U.S. patents by inserting the clause at 52.227-1, Authorization and Consent."). Plaintiffs' sole argument was that the FAR 52.227-1 clauses "may have been modified" in the redacted parts of the publicly available '-0100 Contract. D.I. 21 (Resp.

Br.) at 18–20. The Court noted in its Opinion that, based on the "incomplete and heavily redacted" '-0100 Contract, "any ruling as to authorization and consent would be premature." D.I. 31 at 15. The Court also noted that the "Government ha[d] not filed any statement of interest indicating its express consent to the accused activities." *Id*. at 15–16. As Plaintiffs stated in their Response Brief, "[w]hile not dispositive, courts frequently look to the government's position for evidence on the 'authorization or consent' prong." D.I. 21 (Resp. Br.) at 19–20 (citing *IRIS Corp.* and *Arlton*).

The Government has now confirmed unequivocally that "[t]he inclusion of FAR clauses 52.227-1 and 52.227-1, Alternate I in the '-0100 Contract constitutes the Government's express authorization and consent." SOI at 2, 3 n.5 (offering in camera review of unredacted contract), 8. It is thus beyond dispute that the Government has granted its authorization and consent. *See, e.g.*, *D3D Techs., Inc. v. Microsoft Corp.*, 2021 WL 2194601, at *2 (M.D. Fla. Mar. 22, 2021) (on 12(b)(6) motion, finding "authorization or consent" where "the Government expressly authorized the alleged infringing activity" in the contract); *Arlton v. Aerovironment, Inc.*, 2021 WL 1589302, at *9 (C.D. Cal. Apr. 22, 2021) (finding that "the Government provided authorization and consent" where the contracts at issue contained FAR 52.227-1, Alt. I). The Government's confirmation of the incorporation of the FAR clauses is sufficient.

Moreover, the Government's Statement of Interest provides an independent basis for finding this requirement met. The Government's after-the-fact "authorization and consent" is enough to establish authorization and consent for purposes of § 1498. *See Arlton*, 2021 WL 1589302, at *10 (finding that the "Statement of Interest shows that the Government retroactively authorizes and consents to the Accused Activities"); *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976) (stating that "post hoc intervention of the Government in pending infringement litigation against individual contractors" establishes authorization or consent); *Connell v. KLN Steel Prods. Ltd.*, 2009 WL 691292, at *13 (N.D. Ill. Mar. 16, 2009) (finding on summary judgment that "[t]he Navy's intervention in this litigation removes any ambiguity in previously disputed evidence addressed in this Court's prior opinion and constitutes dispositive evidence of implied authorization and consent"); *see also IRIS Corp.*, 769 F.3d at 1363 (affirming dismissal under 12(b)(6), ***without*** an express authorization and consent clause, noting that the "United States has unequivocally stated its position that suit under § 1498(a) is appropriate here").[3]

[3] The Government's broad authorization and consent also applies to allegations of indirect infringement arising from use of the vaccine, including any liability arising from "administration" to end users as expressly contemplated in the '-0100 Contract. See D.I. 23 at 7–9; *Astornet Techs. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277–78 (Fed. Cir. 2015) (indirect infringement claims barred by § 1498(a) where underlying direct infringement is by the Government); *see also Zoltek Corp. v. United States*, 672 F.3d 1309, 1314–15, 1319 (Fed. Cir. 2012) (finding that "limitation of § 1498(a) to infringement under § 271(a) is inconsistent with the plain language of the statute" and noting that "Section 1498 makes no reference to direct infringement as it is defined in § 271(a)").

C. Moderna's Motion Can Be Granted under Rule 12(b)(6)[4]

As an affirmative defense, Section 1498 immunity provides a basis for dismissal under Rule 12(b)(6) when the elements of the defense appear on the face of the complaint as well as any matter of public record and items subject to judicial notice. *See* D.I. 17 (Mot.) at 7–8 (citing cases and Fed. R. Evid. 201). Nothing in the Complaint contradicts what the Government has confirmed in the Statement of Interest.[5] And significantly, in no case identified by the parties where the Government voiced its position that § 1498 applied did a court disagree.

As to the scope of Moderna's Motion, Moderna only seeks to dismiss what is covered by the Government's authorization and consent—namely, Plaintiffs' claims based on vaccine procured under the '-0100 Contract. Courts can and do dismiss parts of a complaint. *See, e.g.*, *D3D Techs.*, 2021 WL 2194601, at *5 (granting 12(b)(6) motion to dismiss in part "IVAS-based infringement claims" under § 1498(a)); *Iguana, LLC v. Lanham*, 2009 WL 1620586, at *4–5 n.1, 10 (M.D. Ga. June 9, 2009) (granting in part 12(b)(6) motion, dismissing counterclaim under § 1498(a), "to the extent that Lanham is asserting a patent infringement claim against Plaintiff as to Plaintiff's sale and manufacture of its bednets to the United States, this claim is dismissed"). There is simply no reason to litigate claims based on the '-0100 Contract in this case.

To the extent Plaintiffs claim to need discovery into which and how many doses were procured under the '-0100 Contract, Plaintiffs will get that discovery in this litigation, just as any plaintiff gets discovery to prove the quantity of allegedly infringing sales. In fact, immediately after the February 16, 2023 hearing, Plaintiffs served an Interrogatory seeking in part for Moderna to identify each "contract with the U.S. Government" and each of "the batches of the Accused Product that were sold under [each] contract by all batch numbers." Moderna will provide that information regardless of whether the Court grants Moderna's Motion.

D. No Discovery Is Needed to Decide Moderna's Motion

Plaintiffs suggested that discovery would be needed on "whether Moderna was under the Government's control in connection with the development and testing of its vaccines, and its decision to use our invention in its vaccine"; however, discovery is unnecessary. Feb. 16, 2023

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[4] Elevating form over substance, Plaintiffs suggested Moderna's Motion is no longer pending. Feb. 16, 2023 Hr'g Tr. at 30:25–31:1. Although the Court is free to reconsider its decision, it can also treat this briefing as a motion for reargument under Del. L.R. 7.1.5 and 1.1(d) because the "interest of justice" supports considering the Government's Statement. "The purpose of a motion for reconsideration . . . is to correct manifest errors of law or fact or to present newly discovered evidence." *Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). If the Court decides that new briefing is required, Moderna is prepared file a motion for partial judgment on the pleadings under Fed. R. Civ. P. 12(c).

[5] The Court may consider the Government's positions in the Statement, as the Federal Circuit did in affirming a Rule 12(b)(6) dismissal in *IRIS Corp.*, 769 F.3d at 1363. *See also* Fed. R. Evid. 201(b)(2) (judicial notice permitted for facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned").

Hr'g Tr. at 17:1–18:14. There is no question that the Government decided to grant Moderna authorization and consent by including two ***broad*** FAR clauses, consenting to "***all*** use and manufacture of any invention described in and covered by a United States patent in the performance of this contract" and "***all*** use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent – (1) [e]mbodied in the structure or composition of ***any article*** the delivery of ***which is accepted by the Government*** under this contract . . . ." SOI at 4, 9 (quoting FAR 52.227-1, Alt. I and 52.227-1), 9. Acceptance of those goods by the Government "brings the matter within Section 1498 even if the contract could be fulfilled with other noninfringing products." *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 974, 980 (C.D. Cal. 2019) (quoting Chisum; finding that FAR 52.227-1(a)(1) authorized infringement of method and apparatus claims).

The court in *Arlton v. Aerovironment, Inc.* rejected a similar argument that § 1498 did not apply because the contracts could have been satisfied by noninfringing technology. The court found that the "broad [FAR 52.227-1, Alt. I] authorization and consent clause included in the Subcontracts and the Statement of Interest show otherwise," but even "assuming the Government did instruct Defendant to avoid the technology claimed in the '763 Patent, the Statement of Interest shows that the Government retroactively authorizes and consents to the Accused Activities." 2021 WL 1589302, at *10 (C.D. Cal. Apr. 22, 2021); *see also id.* at 9 ("To the extent there was any question whether the Government consented to the use and manufacture of the particular technology described in the '763 Patent, the Government also filed a Statement of Interest in this case providing express consent to the accused activities."). The court further rejected "***as a matter of law***" plaintiffs' argument that they needed discovery into "whether the Government provided any directions to [defendant] to avoid the [plaintiffs'] technology such that consent was either not given, or even expressly revoked," finding it unwarranted. *Id.* at *10–11; *see also TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986) ("To limit the scope of § 1498 only to instances where the Government requires by specification that a supplier infringe another's patent would defeat the Congressional intent to allow the Government to procure whatever it wished regardless of possible patent infringement.").

Although this Court considered the detailed inquiry undertaken in *Larson* (D.I. 31 at 12), that case is distinguishable, as the court there had to examine whether the Government provided ***implied*** authorization and consent, in the absence of a direct contract, through reimbursement of qualifying medical expenses under Medicare, Medicaid, and CHAMPUS:

> Having conceded that there was no express authorization or consent by the government to infringe on the patents, plaintiffs based their argument on an implied authorization by necessity theory. An implied authorization to infringe may be found under the following conditions: (1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement.

26 Cl. Ct. 365, 370 (1992). Moreover, in *Larson*, the Government (as the defendant) argued it did ***not*** provide its authorization and consent such that § 1498 did not apply. Here, no discovery into

these issues is needed, as Moderna relies on ***express*** authorization and consent, and the Government ***agrees*** it provided it.[6]

Plaintiffs also seek burdensome discovery into how millions of doses supplied under the '-0100 Contract were distributed in the U.S.[7] and "documents related to Defendants' understanding of who was the true beneficiary of any contract with the U.S. Government"—none of which is needed in light of the Government's express acceptance of liability. *See supra* Sections I.A–I.B.

E. Discovery Should Not Proceed on Claims That Can Only Be Adjudicated in the Court of Federal Claims

If the Court grants Moderna's Motion, Plaintiffs can pursue a claim against the United States in the Court of Federal Claims under 28 U.S.C. § 1498(a), and this litigation will proceed based on Plaintiffs' remaining claims for batches other than those procured pursuant to the '-0100 Contract. Plaintiffs suggested that if they are successful on their remaining claims in this litigation, the Court of Federal Claims would then only adjudicate damages on claims subject to § 1498(a), and not infringement or invalidity. Feb. 16, 2023 Hr'g Tr. at 16:3–11. Under § 1498(a), however, claims based on the '-0100 Contract can only be adjudicated by the Court of Federal Claims, where the Government would have a full and fair opportunity to litigate noninfringement and invalidity. As the Federal Circuit has explained, "[w]hen a manufacturer sells a product to both the government and a third party, the normal course of events is parallel patent infringement proceedings in the Court of Federal Claims for sales to the government in accordance with 28 U.S.C. § 1498 and in the district court for the nongovernmental sales." *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1580 n.1 (Fed. Cir. 1995).

Plaintiffs have served extensive discovery requests seeking the testing and analysis of the "lipid ratios . . . within ***each batch***" of the Accused Product. Moderna has made hundreds of batches of the Accused Product since the start of the pandemic, with varying formulations. It would be inefficient and unnecessary for the parties to proceed with fact and expert discovery into whether batches procured under the '-0100 Contract infringe the Asserted Patents when ultimately those infringement claims can only be adjudicated in the Court of Federal Claims.

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[6] *Leupold & Stevens, Inc. v. Lightforce USA, Inc.* (cited in D.I. 21 at 19) involved "outstanding questions of fact as to whether the FAR 52.227-1 appears in, and applies to, the contracts at issue." 449 F. Supp. 3d 1015, 1021 (D. Or. 2020). Here, Plaintiffs do not dispute that the '-0100 Contract incorporates FAR 52.227-1. In *Madey v. Duke Univ.* (cited in D.I. 21 at 17), the defendant relied on a "research grant by a federal agency" rather than on express authorization and consent, on which Moderna relies here. 307 F.3d 1351, 1359, 1360 (Fed. Cir. 2002).

[7] Request for Production No. 66 ("All documents related to how doses of the Accused Product were distributed and to whom (including but not limited to customers of drug stores, grocery stores, private medical practices, or on military bases).").

F. Dismissing the '-0100 Contract-Based Claims Aligns with the Policy Behind § 1498(a)

As the Federal Circuit has recognized, "[t]he coverage of § 1498 should be broad so as not to limit the Government's freedom in procurement by considerations of private patent infringement." *TVI Energy*, 806 F.2d at 1060; *see also Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 618 (M.D.N.C. 2006) ("[T]o not find § 1498 applicable here would . . . undermine the Government's ability to obtain goods, services, and research it needed regardless of patent infringement issues."). Although the Government commonly provides "authorization and consent" in the procurement of military goods, neither § 1498(a) nor the FAR 52.227-1 clauses in the '-0100 Contract are limited to military contracts. Indeed, courts have found that § 1498(a) applies to a variety of goods and services supplied to the Government. *See, e.g.*, *Advanced Software Design*, 583 F.3d at 1373 (system for detecting fraudulent checks); *Astornet Techs.*, 802 F.3d at 1274 (use of equipment for scanning airline boarding passes); *Sevenson*, 477 F.3d at 1363 (waste remediation); *IRIS Corp.*, 769 F.3d at 1361 (secure electronic identification documents). The Government's decision to grant Moderna its authorization and consent for nationwide supply of a vaccine amid a global pandemic should be given the same deference as in any other context.

II. CONCLUSION

Moderna respectfully requests that the Court dismiss Plaintiffs' claims based on vaccine procured under the '-0100 Contract.

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/bac

cc: All Counsel of Record (via CM/ECF and electronic mail)